

REMARKS

The Office Action mailed on April 24, 2009 has been reviewed and the comments of the Examiner carefully considered. Claims 1, 3-13, and 19 are pending and currently stand rejected. Claim 1 has been amended. Claim 8 has been canceled. No new matter has been added by way of this amendment.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 3-7, 9, 12 and 19 were rejected under 35 U.S.C. § 102(e) as anticipated by Guo et al. (US 7,252,837). Regarding independent claim 1, the Examiner alleged that Guo et al. “teaches a wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose (see Example 4)”. *Office Action dated April 24, 2009, page 3.*

It is well-settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” See *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) and also MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil C. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the ...claim” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, Guo must describe each and every element of the claims in order to anticipate these claims under section 102(b). However, Guo does not meet this burden.

Applicants respectfully submit that Guo et al. as a whole, and more specifically, in Example 4 as cited by the Examiner, only discloses an oxidized regenerated cellulose (ORC) patch that has been soaked in a solution of dissolved chitosan for three minutes and then lyophilized overnight. Applicants further submit that this does not comprise an “intimate mixture” intimate mixture, as defined by the instant specification, of a chitosan and an oxidized cellulose. The “intimate mixture” of the instant application comprises a mixed solution or dispersion of the chitosan and the oxidized cellulose in a suitable vehicle, such as a solvent, or a solid composition produced by removing solvent from such a solution or dispersion. Such intimate mixing results in maximum chemical complexation between the amine groups of the

chitosan and the carboxylate groups on the oxidized cellulose (*see, e.g.*, the instant specification at page 5, lines 1-2).

However, for the purposes of furthering prosecution and further clarifying the scope of the instant invention only, and without any admission as to the propriety of this rejection, Applicants have also herein amended claim 1 as follows:

Claim 1: (Currently Amended) A wound dressing composition comprising an intimate mixture of a chitosan, ~~and~~ an oxidized cellulose, and from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance.

As Guo et al. does not disclose a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance, the cited reference does not suggest, much less teach, the present invention. Anticipation exists only when the cited reference discloses all the elements, features, or limitations. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Thus, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

Consequently, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(e). Further, applicants submit that claims 3-7, 9, 12 and 19 are thereby allowable as written as depending from an allowable independent claim.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 3-13, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cullen et al. (WO 00/33893). Regarding independent claim 1, the Examiner alleged that while Cullen et al. “does not specifically exemplify a composition comprising both oxidized cellulose and chitosan”, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing comprising an intimate mixture of oxidized cellulose and chitosan because Cullen et al. teaches a sterile composition that can be used as a wound dressing including a therapeutic peptide and a polysaccharide selected from the

group consisting of oxidized celluloses, chitosans and salts “and mixtures thereof”. Furthermore, the Examiner alleged that collagen, ORC and chitosan are art recognized functional equivalents – thus, it would have been obvious to substitute the collagen in Cullen et al. for ORC with a reasonable expectation of success and one would have been motivated to do so since Cullen et al. teaches that collagen and ORC are equally valid wound dressing materials. The Examiner also stated that in the absence of evidence showing that collagen and not ORC is the active ingredient in the collagen/ORC sponge of FIGS. 1-2 of the instant specification, applicants’ data further supports the Examiner’s argument that ORC, collagen and chitosan are equally effective wound composition materials. *Office Action dated April 24, 2009, pages 6-7.*

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103 ...

[T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141)

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II).

Applicants respectfully traverse the rejection for the same reasons stated in the Amendment and Response to Office Action filed on March 23, 2009. In summary, Applicants submit that as disclosed in the present specification, the oxidized cellulose is in the form of particles, such as fiber particles or powder particles, preferably dispersed in a suitable solid or semisolid topical medicament vehicle (*see e.g.*, page 3, lines 25-27). The oxidized cellulose is more thoroughly complexed – *i.e.*, an “intimate mixture” – with the chitosan, as discussed below.

Cullen et al. merely discloses a sterile composition comprising a complex of a therapeutic peptide and a polysaccharide, and therefore fails to suggest, much less disclose, an “intimate mixture of a chitosan and an oxidized cellulose”.

It is a surprising and unexpected result of the present invention that such intimate mixing results in maximum chemical complexation between the amine groups of the chitosan and the carboxylate groups of the oxidized cellulose (page 5, lines 1-2). In addition, the intimate mixture of oxidized cellulose and chitosan, both having a range of controllable properties, renders them readily available and allows an exceptional degree of control of their properties. In particular, the rate of biological absorption, porosity and density of the materials may be controlled (page 7, lines 9-12). Further, it is a surprising and unexpected result that the intimate mixture of the present invention has an excellent ability to bind to growth factors – in particular, platelet derived growth factor (PDGF) (page 10, lines 10-15).

However, for the purposes of furthering prosecution and further clarifying the scope of the instant invention only, and without any admission as to the propriety of this rejection, Applicants have also herein amended claim 1 as follows:

Claim 1: (Currently Amended) A wound dressing composition comprising an intimate mixture of a chitosan, ~~and~~ an oxidized cellulose, and from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance.

Cullen et al. does not provide any teaching or suggestion for the skilled artisan to make or use a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and having from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance. Nor does Cullen et al. provide any motivation to the skilled artisan to arrive at such a composition having those particular levels of individual components. Cullen et al. does not teach or suggest any advantage or necessity to do so.

As Cullen et al. does not provide any suggestion or motivation for the skilled artisan to make or use a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and with from about at least 1% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance, Cullen et al. does not suggest, much less teach, the present invention, and therefore does not provide the skilled artisan with any

reasonable expectation of success in arriving at the presently-pending claims. Obviousness exists only when the prior art reference must teach or suggest all claim limitations. MPEP § 2143.

Consequently, applicants respectfully request reconsideration and withdrawal of the rejection of claim 1, 3-13 and 19 under 35 U.S.C. § 103(a).

Double Patenting Rejections

Claims 1, 3-7, and 9-12 were rejected on the ground of nonstatutory obviousness-type patenting over US Patent No. 7,252,837. Applicants respectfully submit this rejection is improper, and request withdrawal thereof, as the '837 patent is currently assigned to Ethicon, Inc. and thus is not commonly owned with the instant application.

Claims 1, 3-5, 9 and 12 were provisionally rejected over co-pending US Patent Appln. No. 11/609,964. Applicants herein enclose a Terminal Disclaimer for the assignee, executed by the attorney of record, to obviate the Provisional Double Patenting Rejection under 37 C.F.R. § 1.321(c) for co-pending U.S. Patent Appln. No. 11/609,964. Applicants therefore respectfully request allowance of claims 11, 3-5, 9 and 12.

Claims 1 and 3-13 were provisionally rejected over co-pending US Patent Appln. No. 10/579,850. Applicants herein enclose a Terminal Disclaimer for the assignee, executed by the attorney of record, to obviate the Provisional Double Patenting Rejection under 37 C.F.R. § 1.321(c) for co-pending U.S. Patent Appln. No. 10/579,850. Applicants therefore respectfully request allowance of claims 1 and 3-13.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5337 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge the \$140.00 Terminal disclaimer fee (for each Terminal disclaimer enclosed) under 37 CFR 1.20(d) as well as charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5023) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

BREDA M. CULLEN ET AL.

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By: 

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